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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,825	07/17/1998	CHRISTIAN GRONHOJ LARSEN	GRONHOJ-LARS	1107

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/26/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/101,825

Applicant(s)

GRONHOJ LARSEN ET AL

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-41, 47, 49, 50, 52, 53, 57, 59, 61, 63, 65-68 and 70-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-41, 47, 49-50, 53, 59, 61, 63, 65-68, 70-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1a. Receipt of Applicant's amendment canceling claim 69 and adding new claims 83-87, filed on 09 April 2003, in Paper NO.32, is acknowledged. Thus claim 18-22, 24-41, 47, 49-53, 57, 59, 61, 63, 65-68 and 70-87 are pending and under consideration.

1b. The indicated allowability of claims 18-22, 24-41, 63, 65-79 and 80-82 and 51-53, 59 and 61, is withdrawn in view of the following new rejections.

Maintenance of Rejections:

2a. The rejection of claims 49 and 57, made rejected under 35 U.S.C. 112, first paragraph, is maintained for reasons of record set forth in the office action mailed on 12 December 2002, in paper NO:30, on pages 3-5. (Also claim 87 is rejected under this statute). Specifically, instant specification, while being enabling for a method of treating arthritis, pancreatitis and ARDS like syndrome, by administering to a subject in need of said treatment a pharmaceutically effective amount of the non-naturally occurring polypeptide recited in instant claim 18, does not reasonably provide enablement a method of "all" possible diseases treatable by a substance which has the properties recited in a-k of claim 49, or a method of treating cancer, as recited in claim 57, by administering to a subject in need of said treatment a pharmaceutically effective amount of the non-naturally occurring polypeptide recited in instant claim 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants argue that to determine whether a disease is included in claim 49, one need merely attempt to treat it with one of the cited substances. Applicants cite several

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U.S Patents and argue that the type of claims sought in this application, have been previously granted.

These arguments have been considered fully, but are not deemed persuasive. Applicants are merely inviting the skilled artisan to attempt to treat "all" possible diseases with the substances of the instant invention, and see which diseases are treatable and which ones are not. However, to satisfy the requirements of 35 U.S.C. 112, first paragraph, instant specification must provide guidance as to which diseases might be treatable with said substances. Furthermore, there has to be some expectation of success that said diseases are treatable with these substances. It would be undue experimentation for the skilled artisan to conduct the necessary experiments and proper controls to delineate which diseases might be treatable with the substances of the instant invention. Claim 57 which limits the disease to be treated to cancer is also not enabled, because cancer is not one disease, it is a very complex condition which encompasses various types of malignant neoplasms, and all cancers are not caused by the same culprits or treated by the same agents. Therefore, since instant specification has not disclosed one single type of cancer that is treated by the claimed peptide of claim 18, claim 57 is not enabled. With respect to claim 87, it will be undue experimentation to determine "all" possible diseases that are characterized by decreased or insufficient IL-10 activity, because the number of potential diseases are numerous and instant specification only enables a method of treating arthritis, pancreatitis and ARDS like syndrome, by administering to a subject in need of said treatment a pharmaceutically effective amount of the non-naturally occurring

polypeptide recited in instant claim 18. With respect to Applicants' second, Applicants are reminded that each Patent Application is examined on its' own merits and each Patent Application must satisfy the requirements under 35 U.S.C. 112, first paragraph.

2b. The rejection of claims 49, 51-53, 57, 59 and 59 are rejected under 35 U.S.C. 112, second paragraph, is maintained for reasons of record, set forth in the office action mailed on 17 December 2002. The metes and bounds of the claims can not be ascertained, since no specific disease is recited.

Claims 51-53, 57-59, 61 are rejected 35 U.S.C. § 112, second paragraph; insofar as they depend on claim 49.

NEW REJECTIONS:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18-41, 47, 50-53, 57-59, 61, 63, 65-68, 70-87, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

3a. Claim 18 and 76 recite "...said sequence corresponds essentially to the C-terminal of said polypeptide ...", however, instant specification does not describe the structure of a sequence that corresponds essentially to the C-terminal of said polypeptide. Instant specification does not define "corresponds essentially to the C-

terminal ", as a result the skilled artisan can not visualize the structure of the claimed polypeptide.

3b. Claims 18-21, 34, 76 recite ".... the polypeptide is stabilized.....", however, the specification as filed describes only one way of accomplishing said "stabilization", by attaching the small compound with the formula disclosed on the bottom of page 21 of the specification, to the N-terminal of IL-10. Thus, the written description in this case only discloses the attachment of said molecule to the N-terminus of the claimed peptide which makes it resistant to proteolytic degradation. Therefore only the attachment of the small compound with the formula disclosed on the bottom of page 21 of the specification, to the N-terminus of the claimed peptide which makes it resistant to proteolytic degradation, meets the written description provision of 35 U.S.C. 112, first paragraph.

3c. Claim 40 is drawn to a peptidomimetic modeled on the basis of the polypeptide of claim 18, however, instant specification describes only one way of modeling said peptidomemtic on the basis of the claimed peptide. The breadth of the claim is beyond what is disclosed in the specification. Instant specification discloses that the attachment of a small compound with the formula disclosed on the bottom of page 21, to the N-terminal of IL-10 stabilizes the peptide by making it resistant to proteolytic degradation. Thus, while instant specification is enabled for making said modification, it is not enabled for "all" possible petidomimetics modeled on the basis of the peptide of claim 18. The skilled artisan can't visualize the structure of the claimed peptidomimetis, with the exception of attaching the molecule disclosed on page 21, to N-terminus of the

claimed peptide. Therefore, absent any guidance from the specification of the structure of the peptidomimetics claims in the claim, the skilled artisan could not predict said structure. Furthermore, due to the lack of direction or guidance in the specification, the absence of working examples and teachings of the prior art, the unpredictability in the art, and the complex nature of the invention, undue experimentation would be required of the skilled artisan to select all the peptidomimetics that display the desired biological activities.

3d. Claim 73 recites a specific molecular weight for amino acid residues, however, the specification as filed did not disclose said molecular weight, therefore, said recitation is **NEW MATTER**. Thus, the specification fails to provide proper support for said recitation. It appears that Applicants were in possession of peptides that comprise amino acids that did not exceed the recited molecular weight.

3e Claims 80-81 recite "a method of preventing death due to pancreatitis...", however, instant specification has not disclosed any subjects that were prevented from dying by administering the composition of claim 41. Furthermore, "prevention" means determining in advance if a patient is susceptible to a specific disorder and Applicants are not enabled for such. Therefore, due to the lack of direction or guidance in the specification, the absence of working examples and teachings of the prior art, the unpredictability in the art, and the complex nature of the invention, undue experimentation would be required of the skilled artisan to perform the necessary experiments to demonstrate that the administration of peptide of the instant invention would prevent death due to pancreatitis.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22, 24, 39, 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 22 and 76 refer to a Reference Table A, however, this renders the claims indefinite, because the claims must not refer back to other parts of the Application.

Reciting the specific amino acids in the claims would obviate this rejection.

4b. Claim 24 fails to further limit the polypeptide of claim 18.

4c. The term "substantially pure" recited in claim 39 is a relative term which renders the claim indefinite. The term "substantially pure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Conclusion:

5. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

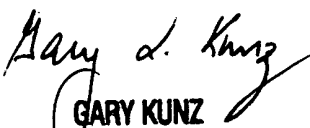
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
August 25, 2003


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